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**NIPRO**

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**SUMMARY OF SAFETY AND EFFECTIVENESS FOR NIPRO®  
DISPOSABLE SOLUTION INFUSION SET**

§807.92 (a)(1)

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§807.92 (a)(2)

Trade Name:

Nipro® Disposable Solution Infusion Set

Common Name:

Disposable Solution Infusion Set or I.V. Administration Set

Classification Name: Intravascular administration set (21 CFR §880.5440)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device: I.V. Administration Set, Gainor  
Medical U.S.A., Inc. (K926448)

§807.92 (a)(4)

Description of Device:

Intravascular administration sets are described in 21 CFR §880.5440. The Disposable Solution Infusion Sets that we intend to market include 4 types of designs. The sets consist of a length of polyvinylchloride tubing with a clamp roller along it and a male luer lock at one end and a non-vented infusion subassembly without filter at the other end. Model number NNC-3L has a male luer-lock connector (without injection site) and NNC-3CL has the male luer-

lock connector and Y-connector with injection site. Model NNC-3CS has the cone luer slip and Y-connector with injection site and NNC-3C has the cone slip connector (without injection site).

The materials used for the components include polyethylene (PE), polyvinylchloride (PVC) (contains DEHP), polypropylene (PP) and acrylonitrile butadiene styrene (ABS). Cyclohexanone and adhesive bond are used and are present in trace amounts.

§807.92 (a)(5)

Intended Use:

The Solution Infusion Sets are intended to be used for the administration of intravenous fluid solution into the body.

§807.92 (a)(6)

Comparison of Technical Characteristics:

The Nissho and Gainor Medical devices are exactly the same devices, therefore, all technical characteristics are identical.

As these sets have been marketed for several years, safety and effectiveness has been established through years of clinical use. There have not been problems reported during use of the sets.